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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,887	01/28/2000	Dr. Norbert Ettner	Beiersdorf 602-WCG	2789

7590 11/26/2001  
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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/26/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/493,887

Applicant(s)

Ettner et al.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 4, 6-10, and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

- ☒ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other: \_\_\_\_\_

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Applicant's response to restriction requirement filed 9/28/01 (paper # 8) is acknowledged. Applicant elected Group IV invention (claims 1-3, 5 and 11-16 ) directed to hydrogels comprising free radical scavenger proteins and methods of producing said hydrogels with traverse. Claims 6-10 and 17-20 are withdrawn.

Applicant is reminded that due to inadvertent error of the examiner claim 4 was incorporated into Group IV invention. However, said claim does not relate to free radical scavenger proteins of Group IV and should therefore be rejoined with Groups such as Group I, II and III. Hence, claim 4 is also withdrawn from further examination as drawn to non-elected invention.

In traversal of restriction requirement applicant argues a search required for one Group relates to all indicated Groups I-VII and hence, the supplemental restriction should be withdrawn. Applicant's argument was fully considered but was found unpersuasive because said Groups as explained previously, are directed to products of distinct structure and function. Further, the searches required for each invention are **not coextensive**. Therefore, restriction is maintained according to previous office action and is hereby made **final**.

Applicant further requests that upon allowance of the elected subject matter, non-elected subject matter to be rejoined with the elected invention. In response the examiner would like to point out that once the elected subject matter becomes allowable she will call the applicant to discuss this issue.

#### **DETAILED ACTION**

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Claims 1-3, and 5 and 11-16 are under examination on the merits.

***Claim Objections***

1. Claims 12 is objected to because of the following informalities: There are several periods in claim 12. See for example, part (f), and part (g). Applicant is advised to remove said periods from said claim. Also it is not clear why the first step of the claim starts with (e) instead of (a). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following are quotations of the first and second paragraphs of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 5, 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims (1-3, 5, 11 ) all start with the term “Hydrogel” which is not correct. Similarly, claims 12-13 all start with “process” instead of “A process. Applicant is advised to replace said terms in said claims with “A hydrogel” or “A process”, respectively.

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4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “has a molecular weight of from 8,000 to 18,000 g/mol, in particular from 10,000 to 15,000 g/mol” is vague and indefinite. It is not clear which range of molecular weight of PEG applicant is referring to, the former or the latter. Applicant is advised to delete one of the claimed molecular weight ranges (i.e. the one with narrower scope) from said claim and optionally introduce a new dependent claim reciting the narrower PEG molecular weight range.

5. Claims 1-3, 5, 11 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “SOD/catalase enzyme mimic” in claim 1 (and its dependent claims 2-3), 11 and 14-16 and claim 5 is indefinite. Applicant did not define this term in the specification. It is not clear whether said mimics have activity and urea groups or not. Applicant is further reminded that in claim 5 he/she is referring to said mimics as proteins which is specially unclear.

6. Claims 1-3, 5, 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “parts of proteins and enzymes” in claims 1 (and its dependent claims 2-3, 11 and 16) is indefinite. This phrase has not been defined in the specification. It is not clear what constitutes a “part”.

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7. Claims 1-3, 5, 11 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (and its dependent claims 2-3, 5, 11 and 16) is grammatically incorrect and confusing. For example, it is not clear what is the difference between hydrogel and PEG. Applicant is advised to rewrite said claim in a more concise manner.

**For examination purposes the examiner is reading the claim as following:**

**“A composition comprising polyethylene Glycol ( PEG) and at least one the following products: proteins, enzymes, SOD/catalase enzyme mimics, parts of said proteins or enzymes, recombinant proteins and enzymes or combinations of any of said products wherein said products or combinations thereof are connected to said PEG via urea groups.”.**

8. Claims 12-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is vague because it is not clear whether it comprises all steps (e)-(h) sequentially and whether it ends with step (h) or not. As mentioned above the presence of several periods makes the claim even more confusing. Claim 13 is rejected for depending from rejected base claim.

Also, in part 12 (e) applicant is advised to replace the confusing term “with the addition: with the term “in the presence”.

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9. *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-3, 5, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fortier (U.S. patent No. 5,733,563, 1998, cited in the IDS) in view of Galin et al. (Makromol. Chem., 175(3), 991-1000, 1974, abstract ) further in view of current wound treatment/protection techniques. Fortier teaches a PEG (polyethylene glycol) hydrogel of a molecular weight of from 2000 to 35000 to which enzymes such as catalase are crosslinked through their amino groups optionally in the presence of albumin, wherein the crosslinking agent is 4-nitrophenyl chloroformate. Fortier does not teach a hydrogel or a method of preparation thereof wherein the PEG activating agent is diisocyanate and wherein said PEG reacts via its urea groups. Galin teaches the reaction of PEG (of molecular weight 2750-10600) with diisocyanates (including 1, 6-hexamethylene diisocyanate) which inherently involves binding of NCO to OH residues of PEG (see abstract) exposing NCO residues of Cyanate in place of OH residues of glycol.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the PEG of Fortier and use diisocyanate activating agent according to Galin in order to develop new processes for PEG crosslinking to enzymes such as SOD or catalase resulting in stable PEG/enzyme hydrogels. One of ordinary skill in the art is motivated in

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preparing SOD or catalase PEG crosslinked hydrogels because Fortier explicitly teaches that PEG-catalase gels prepared by activating with 4-nitrophenyl chloroformate are unstable (see column 14 of Fortier) implying that new improved hydrogel/enzyme cross linking methods should be attempted. Such attempts obviously include changing the chemical structure of activating agent to activators such as diisocyanates of Galin. One of ordinary skill in the art has a reasonable expectation of success in reacting anhydrous PEG of Fortier with diisocyanate of Galin and remove the solvent after PEG activation by washing or filtration, reacting the activated PEG with catalase or SOD in an appropriate buffer and optionally washing the final gel to obtain a purified PEG/enzyme hydrogel complex which can be incorporated into a wound dressing, compress or bandage according to current wound protection techniques. This is because Galin has shown success in activating PEG with diisocyanate by creating CO-NH residues which according to prior art can successfully bind to NH<sub>2</sub> residues on all chemical structures (natural or synthetic) including proteins/enzymes, rendering the claimed invention obvious.

**No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

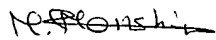
The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.



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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Maryam Monshipouri, Ph.D.

Patent Examiner